REMARKS

I. Amendments to the Specification

The specification has been amended to expressly set forth certain content of the Application No. 10/410,991 ("the '991 application"), now U.S. Patent No. 6,953,787, which was incorporated by reference in its entirety by the current application. *See* current specification, page 1, lines 24-25. The paragraphs inserted between lines 9 and 10 on page 2 can be found on pages 1-2 of the '991 application. The paragraphs inserted after "Summary of the Invention" but before line 15 on page 2 can be found respectively in the third paragraph on page 10, in the second paragraph on page 23, and on pages 11-12 of the '991 application. Accordingly, no new matter has been added.

II. Amendments to the Claims

With entry of this amendment, claims 58 and 62-80 are pending. Claims 1-57 and 59-61 have been canceled without prejudice or disclaimer. Claims 58 and 62-65 have been amended. Claims 66-90 are newly added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

All of these amendments are reasonably conveyed by the specification and original claims. Exemplary support for claim 66 can be found at line 36, page 59 to line 19, page 60 of the current specification and in original claim 650. Exemplary support for claim 67 can be found in the third paragraph on page 10 of the '991 application. Exemplary support for claims 58 and 72 can be found in the second paragraph on page 23 of the '991 application. Exemplary support for claims 62-65, 68-71, and 73-80 can

be found on pages 11-12 of the '991 application. Further exemplary support for claims 71 and 80 can be found on pages 1-2 of the '991 application.

As detailed above, the specification has been amended to specifically set forth the relevant disclosure in the '991 application that provides exemplary support for the new claims. Thus, there is no issue of new matter.

III. 35 U.S.C. §112, First Paragraph

Claims 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. That rejection is moot in view of the current claim amendments. Applicants request that the rejection be withdrawn.

IV. 35 U.S.C. §112, Second Paragraph

Claims 1-6, 8-12, 14, 20, 22-26, 42-45, 47-50, 52-55, 58 and 60-65 are rejected under 35 U.S.C. §112, second paragraph. The Office has expressed concern regarding the scope of R^9, R^{10} and R^{11}, and claims 60 and 61. That rejection is moot in view of the current claim amendments. Applicants request that the rejection be withdrawn.

V. 35 U.S.C. §102

Claims 42-45, 47-50, 52-55, and 58-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al., U.S. 7,704,993 ("the '993 patent"). Claims 42-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al., U.S. 6,953,787 ("the '787 patent"). Applicants respectfully traverse these rejections.

"A claim is anticipated only if *each and every element* as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987)) (emphasis added). Further, a rejection under Section 102 is proper only when the claimed subject matter is *identically* described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587, 172 U.S.P.Q.

(BNA) 524, 526 (C.C.P.A. 1972) (emphasis added). The identical invention must be described in as complete detail as is contained in, and must be arranged as required by, the claim. M.P.E.P. § 2131.

These conditions have not been met, and thus, no valid *prima facie* case of anticipation has been made. Specifically, to the extent that any of the cited prior art references[1] discloses pharmaceutically acceptable salts of 8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazapine, those references do not expressly describe the hydrochloric acid salt of 8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazapine or methods for its preparation. Applicants further note that the cited art does not specifically describe hydrates or solvates of the hydrochloric acid salt of 8-chloro-1-methyl-2,3,4,5-tetrahydro-1H-3-benzazapine. Accordingly, the cited art does not anticipate the presently claimed invention.

Applicants request that the rejection be withdrawn.

VI. 35 U.S.C. §103

The '993 Patent

Claims 42-45,47-50,52-55 and 58-65 are rejected under 35 U.S.C. 103(a) as being obvious over the '993 patent. Applicants respectfully disagree with and traverse this rejection. The '993 patent is not available as prior art against this application per 35 U.S.C. § 103(c).

35 U.S.C. § 103(c) states that effective November 29, 1999, subject matter that qualifies as prior art only under 35 U.S.C. § 102(e) is disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Common ownership may be established by a

[1] The '993 patent is not prior art with respect to at least claim 66, and the claims dependent thereof.

conspicuous statement indicating that the claimed invention and a § 102(e) reference were, at the time the invention was made, commonly owned or subject to an obligation of assignment to the same person. *See* M.P.E.P. § 706.02(l)(2)(II).

STATEMENT REGARDING OBLIGATION OF ASSIGNMENT

The '993 patent is disqualified as prior art under 35 U.S.C. § 103(c), because the present invention and the '993 patent were, at the time the invention was made, subject to an obligation of assignment to the same person, *i.e.*, ARENA PHARMACEUTICALS, INC., as evidenced by the assignment information recorded for the '993 patent recorded at REEL: 0171960 FRAME: 0565 on February 20, 2006 and the assignment information recorded for the instant application at REEL: 019199 FRAME: 0555 on April 24, 2007. *See* M.P.E.P. § 706.02(l)(2)(II). Accordingly, Applicants respectfully submit that the Office cannot rely upon the '993 patent to support the pending § 103 rejection.

Therefore, because the '993 patent does not qualify as legally valid prior art against the present application under 35 U.S.C. § 103(a), Applicants respectfully submit that the rejection is improper and should be withdrawn.

The '993 Patent in View of the U.S. Patent No. 4,541,954

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '993 patent as applied to claims 42-65 above, and further in view of Borowski et al., U.S. 4,541,954 ("the '954 patent"). Applicants respectfully disagree with and traverse this rejection.

This rejection for alleged obviousness relies on the '993 patent. Without the '993 patent, the '954 patent does not disclose or suggest every element of any of the pending claims. Thus, since the '993 patent is not prior art to the pending claims the Office has not made out a *prima facie* case that any of the pending claims is obvious and the rejection for alleged obviousness should be withdrawn.

The '787 Patent

Claims 42-65 are rejected under 35 U.S.C. 103(a)as being obvious over the '787 patent. Applicants respectfully disagree with and traverse this rejection. The '787 patent is not available as prior art against this application per 35 U.S.C. § 103(c).

35 U.S.C. § 103(c) states that effective November 29, 1999, subject matter that qualifies as prior art only under 35 U.S.C. § 102(e) is disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Common ownership may be established by a conspicuous statement indicating that the claimed invention and a § 102(e) reference were, at the time the invention was made, commonly owned or subject to an obligation of assignment to the same person. *See* M.P.E.P. § 706.02(l)(2)(II).

STATEMENT REGARDING OBLIGATION OF ASSIGNMENT

The '787 patent is disqualified as prior art under 35 U.S.C. § 103(c), because the present invention and the '787 patent were, at the time the invention was made, subject to an obligation of assignment to the same person, *i.e.*, ARENA PHARMACEUTICALS, INC., as evidenced by the assignment information recorded for the '787 patent recorded at REEL: 013966 FRAME: 0046 on April 10, 2003 and the assignment information recorded for the instant application at REEL: 019199 FRAME: 0555 on April 24, 2007. *See* M.P.E.P. § 706.02(l)(2)(II). Accordingly, Applicants respectfully submit that the Office cannot rely upon the '787 patent to support the pending § 103 rejection.

Therefore, because the '787 patent does not qualify as legally valid prior art against the present application under 35 U.S.C. § 103(a), Applicants respectfully submit that the rejection is improper and should be withdrawn.

The '787 Patent in View of the '954 Patent

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '787 patent[2] as applied to claims 42-65 above, and further in view of the '954 patent. Applicants respectfully disagree with and traverse this rejection.

This rejection for alleged obviousness relies on the '787 patent. Without the '787 patent, the '954 patent does not disclose or suggest every element of any of the pending claims. Thus, since the '787 patent is not prior art to the pending claims the Office has not made out a *prima facie* case that any of the pending claims is obvious and the rejection for alleged obviousness should be withdrawn.

VII. Double Patenting

1. Claims 42-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 75-104 of copending Application No. 12/729,026.

The Office alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formulae Va and Vb embrace the compounds, compositions and method of use of the compounds of formula I where R_1 is H or C_{1-8} alkyl; R_2 is C_{1-4} alkyl, $-CH_2-O-C_{1-4}$ alkyl, C_{1-4} haloalkyl or CH_2OH; and R_3, R_4, R_5 and R_6 are each independently H, C_{1-4} alkyl, amino, cyano, halogen, C_{1-4} haloalkyl, nitro or OH. Applicants respectfully traverse.

The claims, as amended, are directed to the hydrochloric acid salt of the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine, a solvate, a hydrate, compositions, or methods of use thereof.

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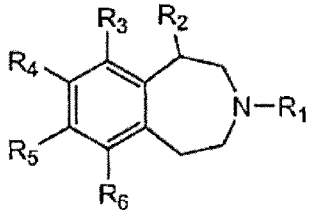
[2] Applicants note that Office action refers in this rejection to U.S. 7,704,993. See, section 10 of the Office action. Applicants believe that the Office intended to refer to the '787 patent rather than the '993 patent as the '993 patent in combination with the '954 patent had previously been applied to the claims in section 8 of the Office action. If Applicants are mistaken, Applicants request clarification of this rejection and an opportunity to respond to it.

Claims 75-104 of the '026 Application depend on claim 1. Claim 1 of the '026 Application is directed to compounds of formula I:



(I)

where when R_2 is C_{1-4} alkyl, $-CH_2-O-C_{1-4}$ alkyl, and CH_2OH; then R_3 and R_6 are not both hydrogen. By contrast, in the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine recited in the amended claims, R_2 is methyl, i.e., C_1 alkyl, and both R_3 and R_6 are hydrogen. Therefore, the claims of the '026 Application expressly exclude the compound recited in the instant claims by requiring that R_3 and R_6 are not both hydrogen when R_2 is C_{1-4} alkyl. There is no suggestion or direction for a person of ordinary skill in the art to prepare a compound that is expressly excluded, and in fact, such a person would be taught away from making such a compound. As such, the instant claims are not obvious over claims of the '026 Application and withdrawal of this rejection is respectfully requested.

2. Claims 54, 55, 58 and 60-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-31 of copending Application No. 11/793,473.

Pursuant to MPEP 804 I(B)1, if a provisional nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the two pending applications, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

Applicants submit that the instant application, which was filed on June 16, 2004, was filed earlier than the '473 Application, which was filed as a national stage

application of PCT/US2005/046983 filed on December 20, 2005. Therefore, Applicants will not address the merit of the provisional obviousness double patenting rejection but request that the Office permit the application to issue without a terminal disclaimer upon withdrawal of other rejections.

3. Claims 42, 45 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 of copending Application No. 12/225,966.

Again, Applicants submit that the instant application was filed earlier than the '966 Application, which was filed as a national stage application of PCT/US2007/008170 filed on April 2, 2007. Therefore, Applicants will not address the merit of the provisional obviousness double patenting rejection but request that the Office permit the application to issue without a terminal disclaimer upon withdrawal of other rejections.

4. Claims 47-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/573,196.

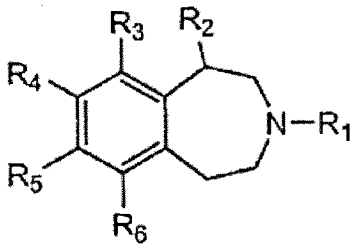
Applicants submit that the '196 Application has become abandoned and therefore this rejection is moot.

5. Claims 42-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 11/599,050.

Applicants respectfully request that this rejection be held in abeyance. Applicants will address this rejection upon indication of allowable subject matter.

6. Claims 42-45, 47-50, 52-55 and 58-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-39 of U.S. Patent No. 7,704,993.

Claims 26-39 of the '993 Patent depend on claim 1. Claim 1 of the '993 Patent is directed to compounds of formula I:



(I)

where when R_2 is C_{1-4} alkyl, $-CH_2-O-C_{1-4}$ alkyl, and CH_2OH, then R_3 and R_6 are not both hydrogen. By contrast, in the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine recited in the amended claims, R_2 is methyl, i.e., C_1 alkyl, and both R_3 and R_6 are hydrogen. Therefore, the claims of the '993 Application expressly exclude the compound recited in the instant claims by requiring that R_3 and R_6 are not both hydrogen when R_2 is C_{1-4} alkyl. A person of ordinary skill in the art would not be motivated to prepare a compound that is expressly excluded, and in fact, such a person would be taught away from making such a compound. As such, the instant claims are not obvious over claims of the '993 Patent and withdrawal of this rejection is respectfully requested.

7. Claims 60-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 7,514,422.

As amended, the claims are directed to the hydrochloric acid salt of the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine, solvate, hydrate, composition or method of the salt. The claims of the '422 Patent are directed to methods of decreasing food intake etc., using a compound of formula I as recited in claim 1 of the '422 Patent. Applicants note that claims 13, 37, and 49 of the '422 Patent are directed to using the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine or a pharmaceutically acceptable salt, solvate or hydrate thereof in these

methods. Applicants submit that these claims do not, nor do any other claims of the '422 Patent, provide any teaching, suggestion or direction for a person skilled in the art to choose the particular hydrochloric acid salt among the many possible pharmaceutically acceptable salts of the compound. Therefore, the claims, as amended, are not obvious in view of the claims of the '422 Patent. Withdrawal of the rejection is respectfully requested.

8. Claims 42-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-77 of U.S. Patent No. 6,953,787.

As amended, the claims are directed to the hydrochloric acid salt of the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine, solvate, hydrate, composition or method of the salt. Applicants note that claim 30 of the '787 Patent recites the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine or a pharmaceutically acceptable salt, solvate or hydrate thereof. Applicants submit that this claim does not, nor do any other claims of the '787 Patent, provide any teaching, suggestion or motivation for a person skilled in the art to choose the particular hydrochloric acid salt among the many possible pharmaceutically acceptable salts of the compound. Therefore, the claims, as amended, are not obvious in view of the claims of the '787 Patent. Withdrawal of the rejection is respectfully requested.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or

absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 11-17-10

By _____

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